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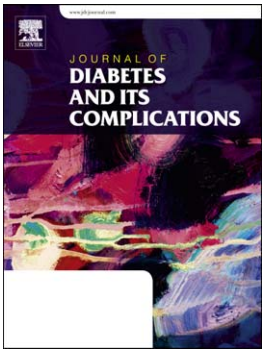

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What is diabetes distress and how can we measure it? A narrative review and conceptual model

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Abstract

Background
Diabetes distress is the negative emotional impact of living with diabetes. It has tangible clinical importance, being associated with sub-optimal self-care and glycemic control. Diabetes distress has been operationalized in various ways and several measures exist. Measurement clarity is needed for both scientific and clinical reasons.

Objectives
To clarify the conceptualization and operationalization of diabetes distress, identify and distinguish relevant measures, and evaluate their appropriateness for this purpose.

Results
Three measure were identified: Problem Areas in Diabetes (PAID) scale, Diabetes Distress Scale (DDS); Type I Diabetes Distress Scale (T1-DDS), Diabetes-specific Quality of Life Scale-Revised (DSQoLs-R) 'Burden and Restrictions - Daily Hassles' sub-scale, Well-being Questionnaire 28 (W-BQ 28) 'Diabetes Well-being' sub-scale, and Illness Perceptions Questionnaire – Revised (IPQ-R) 'Emotional Representations' sub-scale. Across these measures a broad spectrum of diabetes distress is captured, including distress associated with treatment regimen, food/eating, future/complications, hypoglycemia, social/interpersonal relationships, and healthcare professionals. No single measure appears fully comprehensive. Limited detail is reported of the qualitative work informing scale design, raising concerns about content validity.

Conclusions
Across the available measures diabetes distress is seemingly comprehensively assessed and measures should be considered in terms of their focus and scope to ensure the foci of interventions are appropriately targeted.

Keywords: diabetes distress; patient-reported outcome measures; validity; narrative review.

1. Introduction

Living with diabetes is complex and involves various self-care activities, e.g. medication taking, healthy eating, carbohydrate counting, physical activity, checking blood glucose, and problem solving (Peeples et al., 2007). These self-care behaviors are required to keep glycated hemoglobin (HbA1c) in target range, to prevent/delay onset of devastating complications (American Diabetes Association, 2003). The burden of self-management, living with diabetes-related complications (or the risk of their development), and managing difficult social situations, have the potential to cause considerable emotional distress. In the mid-1990s, the emotional impact of living with diabetes was brought to the fore, with introduction of the concept of 'diabetes distress' (DD) (Polonsky et al., 1995). DD emerged from research on stress and coping, and emotional regulation in response to specific acute or chronic stressors, which suggests that emotions can emerge from specific situational contexts and that emotional distress is a response to perceptions of health threats balanced against an appraisal of available coping resources (Fisher, Gonzalez, & Polonsky, 2014).

In recent years, research into DD has gained significant traction. Around one quarter of UK adults with diabetes experience elevated, or severe, DD at any given time (Dennick et al., 2016; Sturt, Dennick, Due-Christensen, & McCarthy, 2015). Similar rates are reported elsewhere in Europe (Stoop et al., 2014), Australia (Speight et al., 2011) and the USA (Fisher, Skaff, et al., 2008). Almost 50% of people experience elevated DD over an 18-month period (Fisher, Skaff, et al., 2008). It should be noted, though not the focus of this review, that DD is additionally well-documented among partners of those with diabetes (Polonsky, Fisher, Hessler, & Johnson, 2016), children and adolescents with diabetes (Hagger, Hendrieckx, Sturt, Skinner, & Speight, 2016) and parents of children and adolescents with diabetes (Johnson, 2013). Indeed, measures of DD specific to the needs of these populations have been developed (Markowitz et al., 2012; Polonsky et al., 2016; Weissberg-Benchell & Antisdel-Lomaglio, 2011).

DD is positively associated with HbA1c, such that fluctuations in each correspond over time (Aikens, 2012; Fisher et al., 2010; Fisher et al., 2007; Schmitt, Reimer, Kulzer, Haak, Gahr, et al., 2015), and reductions in DD are accompanied by clinically significant improvements in HbA1c (Strandberg, Graue, Wentzel-Larsen, Peyrot, & Rokne, 2014; Zagarins, Allen, Garb, & Welch, 2012). DD also impacts upon certain self-management behaviors (Aikens, 2012; Fisher et al., 2007). These relationships have primarily been associative, however, and hence do not indicate causality. Individuals with high DD are less likely to participate in educational and self-management interventions (Fonda, McMahon, Gomes, Hickson, & Conlin, 2009), and exhibit less improvement in HbA1c following such interventions (Weinger & Jacobson, 2001). Conversely, when interventions target DD, individuals with elevated DD engage to a greater extent and this results in improved DD, self-management and HbA1c (Sturt, Mccarthy, et al., 2015). This emerging evidence has prompted calls for further interventions to target DD (Fisher et al., 2007).

From a clinical perspective, measurement clarity is crucial to ensure appropriate identification of need and tailoring of care. From a scientific perspective, it is necessary to ensure valid operationalization of constructs, maximum responsiveness of measures to enable demonstration of effective interventions, and appropriate interpretation of data (U.S. Department of Health and Human Services, 2009). US and European regulatory bodies have released guidance on the development and use of patient-reported outcome measures (PROMs), describing the scientific rigor with which such measures must be developed to enable meaningful measurement and outcomes evaluation (European Medicines Agency Committee for Medicinal Products for Human Use, 2005; U.S. Department of Health and Human Services, 2009). First among the issues discussed is content validity, i.e. the extent to which a questionnaire measures what is claimed. A 'conceptual model' provides a representation of the relevant concepts that comprise the construct, and the

relationships among the concepts. It should be developed, following a systematic literature review and qualitative work with patients and health professionals, to inform the structure and content (items) of a new questionnaire.

In the academic literature, the concept of DD has been assumed to be relatively simple. However, definition and measurement have been circular. DD is defined largely with reference to the issues measured by the Problem Areas in Diabetes (PAID) scale (Polonsky et al., 1995), which is widely regarded as the first PROM to assess DD in adults. Thus, the PAID is widely considered a suitable measure of DD. The more recently developed Diabetes Distress Scale (DDS) (Polonsky et al., 2005) is also gaining traction as a measure of DD in adults. Recent research has suggested that there are important content differences between the PAID and the DDS (Schmitt, Reimer, Kulzer, Haak, Ehrmann, et al., 2015). Until the emergence of the DDS, there had been little discussion about what comprises DD or of the rationale for questionnaire selection. Indeed, it is unclear whether other questionnaires might also be suitable for assessing DD.

Furthermore, while many clinicians/researchers refer to the PAID and DDS (seemingly) appropriately as measures of DD, others have used broader terminology, such as (diabetes-specific) quality of life (Tang, Brown, Funnell, & Anderson, 2008) and diabetes-dependent impairment (Kempf & Martin, 2013). Similarly, measures assessing other constructs (e.g. the ATT-39, which assesses diabetes attitudes and beliefs) have been reported as measures of DD (Esbitt, Tanenbaum, & Gonzalez, 2013; Snoek, Bremmer, & Hermanns, 2015). Beyond operationalizing DD with the PAID or the DDS, a common understanding of how to conceptualize DD and differentiate it from other commonly assessed constructs has not yet emerged in the literature.

Previous reviews have disentangled the conceptualization and measurement of other diabetes-specific PROMs (Garratt, Schmidt, & Fitzpatrick, 2002; Polonsky, 2000; Speight, Reaney, & Barnard, 2009). Recently, researchers have also sought to clarify the conceptual distinction between DD and depression (Fisher, Gonzalez, et al., 2014; Fisher et al., 2010; Fisher et al., 2007; Snoek et al., 2015). To date there has been no attempt to derive a conceptual model of DD, identify and distinguish measures of DD from the vast array of other diabetes-specific PROMs, and explore their validity for this purpose.

Thus, our overall aims were to: a) conceptualize and operationalize DD; b) identify measures of the broad concept of DD by examining their face validity in terms of measuring DD (i.e. the extent to which a measure looks as though it measures DD); and c) review the content validity of the identified measures in terms of assessing DD (i.e. the aspects of DD covered and the extent to which it is likely that each measure captures DD comprehensively) with a view to offering guidance on the context-specific selection of measures.

2. Materials and methods

We began by considering existing definitions of DD in order to derive a common understanding of its conceptualization and operationalization. Several definitions (Aikens, 2012; Esbitt et al., 2013; Fisher, Gonzalez, et al., 2014; Polonsky, 2000; Polonsky et al., 1995; Schmitt, Reimer, Kulzer, Haak, Gahr, et al., 2015; Welch, Jacobson, & Polonsky, 1997) have been applied over the past 20 years, ranging from a brief early description (e.g. “Breadth of emotional responses to diabetes” (p755) (Polonsky et al., 1995) to more recent detailed explanations (e.g. “Significant negative psychological reactions that are specific to one’s diabetes diagnosis, potential or actual complications, self-management burdens, difficult patient-provider relationships, and problematic interpersonal relationships” (p2472) (Aikens, 2012). In summary, DD is characterized as a range of negative emotional responses (e.g. worry, fear, frustration, guilt, sadness, anger, overwhelm), to aspects of

living with and managing diabetes balanced against an appraisal of available coping resources. Living with and managing diabetes comprises many aspects (e.g. self-care, problem-solving, interpersonal relationships), each of which may be associated with a certain amount of emotional distress that can vary over time within and between individuals/sub-groups of people with diabetes. For example, sources and severity of distress can differ between those with type 1 and type 2 diabetes, and those managing type 2 diabetes with different treatment regimens (Baek, Tanenbaum, & Gonzalez, 2014; Tanenbaum, Kane, Kenowitz, & Gonzalez, 2016). These definitions offer insights into the conceptualization of DD and hence inform its operationalization. However, many are vague, and none is fully comprehensive. Collectively, they suggest that measures of DD need to focus on the emotional distress associated with everyday aspects of living with diabetes.

The literature is replete with conceptual overlap between DD and diabetes-specific quality of life. We conceptualize the latter as the extent to which aspects of life (e.g. working life, family life, social life, finances, etc.) contributing to overall quality of life may be impaired by living with and managing diabetes. Diabetes can have a negative impact on quality of life without causing severe emotional distress, though the reverse is less likely to be true. Thus, measures of diabetes-specific quality of life elicit a *cognitive* response (considered thoughts) about the extent of the impact of diabetes on important aspects of life. This is contrast to DD, which is the *emotional* response to specific aspects of living with and managing diabetes.

2.1 Identification and selection of measures

We considered all diabetes-specific PROMs (suitable for completion by adults) eliciting the personal impact of diabetes, hence excluding measures that were evidently not focused on DD (e.g. diabetes knowledge and self-care). We identified the measures while conducting a published systematic review (Dennick et al., 2016; Sturt, Dennick, Hessler, et al., 2015) and by hand-searching published reviews of diabetes-specific PROMs (Eigenmann, Colagiuri, Skinner, & Trevena, 2009; El Achhab, Nejjari, Chikri, & Lyoussi, 2008; Hirsch, Bartholomae, & Volmer, 2000; Luscombe, 2000; Watkins & Connell, 2004). Any additional measures of potential relevance known to the authors were also included. Copies of the questionnaire and development work were obtained (e.g. from published papers, the internet, or direct from authors). We included measures with published psychometric properties and at least one citation of the development work in the previous year (Web of Science, December 2014), and abstracts published within the past three years (but with no citations) considered to be potentially 'emerging' measures. We considered only the full version of each measure, rather than short-form instruments. Where measures had been revised or English language papers had subsequently been published, these revised measures, and the associated development papers, were considered.

2.2 Assessment of face validity

Measures were assessed independently by two authors (KD/JSt) in terms of their face validity as a measure of DD (i.e. regardless of existing descriptions of their purpose by the scale developers or other authors). Decisions were verified, disagreements resolved, and consensus achieved through discussion with a third author (JSp). We applied the following criteria when considering the content of full measures and their constituent, validated sub-scales:

1. Do the items relate to aspects of living with and managing diabetes (i.e. offering reasonable certainty that the person's response relates to their diabetes)? For example, measures excluded would refer to aspects of life, activities of daily living, or social support rather than to diabetes, or have limited scope, focusing on an aspect of diabetes not necessarily specific to this, e.g. diet, exercise, anxiety or depression.
2. Do the items elicit the emotional distress in relation to the above via their item wording? Or, do the completion instructions (or response options) prompt respondents to focus on

emotional distress? For example, measures excluded would refer to how people *think* about diabetes and its impact upon their lives rather than to how they *feel* about their diabetes.

Where some but not all items were considered to assess DD, we determined that, for a measure to assess DD, at least 75% of the items would need to assess the emotional distress associated with diabetes.

2.3 Review of content validity

We explored content validity for assessing DD by contrasting the focus and scope of the identified measures in terms of the aspects of DD included and the detail associated with each respectively.

3 Results

3.1 Identification and selection of measures

Figure 1 illustrates the selection process in a flow diagram. Fifty-three diabetes-specific PROMs for adults were identified, of which 37 had evidence of psychometric validation. Twenty-nine of these were measures of the personal impact of diabetes, of which 19 met our citation criteria and could be obtained. Citations, and the results from the citation search, for the excluded measures are available (online Appendix). The 19 short-listed measures assessed comprise 91 single-factor scales or sub-scales, of which 62 assess the personal impact of diabetes.

FIGURE 1

3.2 Face validity

3.2.1 Measures of DD

Table 1 illustrates the consensus decisions for each of the measures/sub-scales that were assessed. Three full measures and three sub-scales had sufficient face validity to be considered measures of DD:

- PAID (Polonsky et al., 1995)
- DDS (Polonsky et al., 2005)
- Type I Diabetes Distress Scale (T1-DDS) (Fisher, Polonsky, et al., 2014; Fisher et al., 2015)
- 'Diabetes-specific Well-being' sub-scale of the Well-Being Questionnaire 28 (W-BQ28) (Bradley, 2000; Speight & Bradley, 2002; Speight, Khagram, & Davies, 2012)
- 'Burdens and Restrictions - Daily Hassles' sub-scale of the Diabetes-specific Quality of Life Scale (DSQoLs-R) (Bott, Muhlhauser, Overmann, & Berger, 1998; Cooke et al., 2013)
- 'Emotional Representations' sub-scale of the Illness Perceptions Questionnaire – Revised (IPQ-R) (with 'diabetes' substituted for 'illness' as advocated by the authors) (Moss-Morris et al., 2002; Weinman, Petrie, Moss-Morris, & Horne, 1996)

TABLE 1

Table 2 provides a brief description of the content of the scales/sub-scales assessing DD, example items, the published development work, and the results from the citation search. The items in these measures enquire about various aspects of living with and managing diabetes; responses to two DDS items and one T1-DDS item cannot be specifically attributed to diabetes via the item wording but this is ensured via the completion instructions. Emotional distress is largely elicited via the item wording (e.g. DDS: 'Feeling angry, scared and/or depressed when I think about living with diabetes'; DSQoLs-R 'Burdens and Restrictions - Daily Hassles' sub-scale: 'It bothers me that I have to spend so much time on my diabetes'). Where this is not the case, DD is elicited by the instructions and response options (e.g. PAID instructions: 'Which of the following diabetes issues are currently a 'problem' for you?', PAID response options: 'not a problem – serious problem').

TABLE 2

3.2.2 Measures that capture elements of DD but with limited scope

Eight scales/sub-scales were considered to capture elements of DD but be too limited in scope (Table 1). For example, the Hypoglycemia Fear Survey II (HFS-II) 'Worry' sub-scale (Cox, Irvine, Gonder-Frederick, Nowacek, & Butterfield, 1987) requires respondents to indicate how much they have worried about each issue (item) because of low blood glucose. The content is relevant to DD but highly focused on a specific aspect of living with diabetes (i.e. hypoglycemia). Similarly the Inhaled Insulin Treatment Questionnaire (IITQ) 'Diabetes Worries' sub-scale (Rubin & Peyrot, 2010) captures only worry related to hypo- and hyperglycemia and long-term complications. Some Diabetes Symptom Checklist-Revised (DSC-R) sub-scales (Arbuckle et al., 2009; Grootenhuis, Snoek, Heine, & Bouter, 1994) capture the emotional distress associated with diabetes symptoms. The emotional distress associated with other aspects of living with and managing diabetes is missing from these measures, thus they are too limited in scope to be considered measures of DD.

3.2.3 Measures that do not assess DD

Several measures either do not capture DD at all or are insufficiently focused on the construct (i.e. DD is assessed in fewer than 75% of the scale or sub-scale items). Rather, these measures typically elicit cognitive appraisal of the personal impact of diabetes, in other words people's thoughts about the extent to which diabetes impacts on important aspects of their life, yet not the emotional distress associated with this (e.g. Multi-dimensional Diabetes Questionnaire (MDQ) 'General Perceptions of Diabetes' sub-scale: 'To what extent does your diabetes interfere with your daily activities?' (Talbot, Nouwen, Gingras, Gosselin, & Audet, 1997); Audit of Diabetes-Dependent Quality of Life (ADDQoL): 'If I did not have diabetes my family life would be.....' (Bradley et al., 1999); Appraisal of Diabetes Scale (ADS): 'How much is your quality of life affected by the food restrictions required to control your diabetes?' (Boyer & Earp, 1997). Some of these measures also comprise items that tap closely related but distinct constructs, for example self-efficacy and coping (Figure 1). The Questionnaire on Stress in Patients with Diabetes (QSD-R) (Duran, Herschbach, Waadt, Strian, & Zettler, 1995; Herschbach et al., 1997) is constructed such that the completion instructions/response options, and/or the item wording (e.g. 'at times I can't help worrying that I will develop complications later in life'), elicit emotional distress. However, many items do not enquire specifically about diabetes (e.g. 'I suffer from wind') or are cognitively framed, i.e. asking what people think rather than how they feel. It is likely to be more appropriate to consider such measures as assessing the related concept of diabetes-specific quality of life than DD.

3.3 Content validity

There was considerable variability in the operationalization of DD and therefore the focus and scope of the identified measures. Table 3 illustrates the aspects of DD included in each measure. Items were tabulated into categories based on distinct aspects of living with and managing diabetes, initially borne out of consideration of the empirically established DDS sub-scales (Polonsky et al., 2005). Sub-categories were then distinguished using a bottom up approach. We mapped items onto the broad construct of DD where we considered that it had the best fit, so any mismatch is our own and not necessarily that intended by the questionnaire developers. The shading indicates that two or more measures capture that particular aspect of DD, with the corresponding items appearing adjacently. Various aspects of DD are covered across the measures, yet there is considerable variability between them. No measure is fully inclusive; each one evidences omissions relative to the others. The measures are also variable in their coverage of some of the aspects of DD that are included; some operationalize an issue with a single item whereas others use several.

TABLE 3

3.3.1 Treatment regimen

The PAID, DDS, and the T1-DDS, each capture the distress associated with feeling guilty and a failure, and unmotivated and despondent, in relation to the treatment regimen. The DDS is more comprehensive than the PAID and the T1-DDS is particularly thorough in this endeavor. The TI-DDS, and the W-BQ 28 and DSQoLs-R sub-scales, capture treatment burden-related distress and the DSQoLs-R sub-scale has a narrow focus specifically on this. Indeed, treatment-regimen distress is frequently endorsed as a serious problem by diabetes research participants, especially those using insulin (Delahanty et al., 2007; Fisher, Polonsky, et al., 2014; Tanenbaum et al., 2016), and research has shown that it may have the largest and most uniform effect upon diabetes outcomes relative to other aspects of DD, especially in type 1 diabetes (Polonsky et al., 2005; Strandberg et al., 2014). Developed specifically for people with type 1 diabetes, it is unsurprising that the T1-DDS and the DSQoLs-R sub-scale focus on these aspects of DD. The DSQoLs-R was also not originally conceived as a measure of DD, which would explain its limited scope.

3.3.2 Food/eating

Emotional distress surrounding food and eating also ranks high amongst concerns for people with diabetes (Delahanty et al., 2007; Kokoszka et al., 2009; Tanenbaum et al., 2016). The PAID, DDS, T1-DDS and DSQoLs-R sub-scale offer variable coverage of this, with the PAID and T1-DDS being most inclusive, whilst the W-BQ28 omits this.

3.3.3 Hypoglycemia

The T1-DDS, and to a lesser extent the PAID, uniquely elicit distress associated with hypoglycemia, despite the fact that fear of hypoglycemia is well recognized as a distressing aspect of diabetes (Delahanty et al., 2007; Kokoszka et al., 2009; Tanenbaum et al., 2016) and has been demonstrated to have a major impact on diabetes outcomes (Wild et al., 2007). Early measures may offer limited coverage of this element of DD because they were not developed specifically for insulin-treated diabetes and the use of insulin as a treatment option for type 2 diabetes has emerged in more recent years.

3.3.4 Future/complications

Worry about the future and the threat of complications has also been shown consistently, across many studies, to be a frequently endorsed concern amongst people with diabetes (Delahanty et al., 2007; Kokoszka et al., 2009; Tanenbaum et al., 2016). Most of the measures, except the DSQoLs-R and IPQ-R sub-scales, elicit distress associated with concern about complications and/or the future, albeit only the PAID additionally captures distress associated with existing complications. That said, across these measures there is typically greater attention to daily treatment burden than distress associated with complications. There is evidence, however, that people not using insulin to manage their diabetes worry more about co-morbid medical conditions than more immediate issues, such as daily treatment burden (Tanenbaum et al., 2016).

3.3.5 Negative emotional experiences related to diabetes

Both the PAID and DDS offer coverage of the aspects of DD resulting from negative emotional experiences of living with diabetes, rather than practical or behavioral aspects of diabetes, such as monitoring blood glucose, albeit the PAID does so more comprehensively. These PAID items evidence the greatest association with depressive symptoms (Kokoszka et al., 2009) and it is the co-morbidity of DD and low mood that seems to have the greatest impact upon HbA1c (Schmitt, Reimer, Kulzer, Haak, Gahr, et al., 2015). The T1-DDS and the DSQoLs-R sub-scale largely or entirely omit this aspect of DD. It may be that treatment burden supersedes the negative emotional experiences of living with type I diabetes. The W-BQ 28 sub-scale predominantly taps this element of DD with a focus on negative affect and acceptance, and the IPQ-R exclusively captures this. This is

unsurprising given these are primarily measures of emotional well-being, with the W-BQ 28 enquiring about diabetes generally (rather than specific aspects of managing diabetes) and the IPQ-R sub-scale eliciting aspects of distress resulting from negative emotional experiences that are applicable across illnesses.

3.3.6 Social/interpersonal

Both the W-BQ 28 and DSQoLs-R sub-scales omit distress associated with interpersonal issues and social support, whilst the other measures offer variable coverage of this issue. A body of evidence indicates that positive and negative social support behaviors have significant implications for self-management (Tang et al., 2008), for instance spousal disregard for the treatment regimen and tempting with so-called 'forbidden' foods (Henry, Rook, Stephens, & Franks, 2013). The T1-DDS also uniquely elicits distress associated with an additional aspect of interpersonal DD not included in the other scales; fear of discrimination in relation to employment.

3.3.7 Health care professionals

The DDS and T1-DDS, and to a lesser extent the PAID, elicit distress associated with health care professional interactions, while the sub-scales do not capture this issue at all. People with diabetes report that the support (or lack of support) – informational, instrumental, emotional – from health care professionals is pivotal to emotional well-being and expertise in self-management (Balfe et al., 2013; Furler et al., 2008; Thorne & Paterson, 2001). The PAID items were initially developed via patient interviews but also in consultation with health care professionals; perhaps provider-related distress was less likely to be elicited. Indeed, health care professionals cannot be presumed to understand every aspect of DD as people with diabetes would experience it.

4 Discussion

We identified three full measures and three sub-scales assessing DD. A number of other measures capture a very narrow aspect of this construct (e.g. hypoglycemia-related distress), and many other measures elicit a cognitive reflection on, rather than emotional reaction to, diabetes (i.e. items elicit how they *think* rather than how they *feel* about diabetes).

The identified measures capture many aspects of DD as a whole, yet there is marked variability between them in terms of their focus and scope. None is fully inclusive. It has been reported previously that the PAID covers a greater variety of emotional concerns, and has a stronger focus on distress associated with food and eating, existing complications, and hypoglycemia, while the DDS focuses on health care professional and treatment regimen distress (Schmitt, Reimer, Kulzer, Haak, Ehrmann, et al., 2015). This finding is somewhat unsurprising given distinctions in the developer's goals, and some of the relative omissions may reflect imbalance in the populations from which the items were derived in accordance with these aims. For example, numerous aspects of DD that are unique to type 1 diabetes have recently been identified (Balfe et al., 2013; Fisher et al., 2015) and this formed the basis for developing the T1-DDS (Fisher et al., 2015). They may also reflect distinctions in methodological approach; the DDS items reflect four domains considered central to diabetes-related emotional distress created a priori based on focus groups discussions whereas the PAID was not apparently informed by any such structure when it was developed 10 years earlier.

The detail communicated about the development work informing scale design is also variable yet typically limited, though, in particular for the older measures. Explicit description of development work is critical so that readers are able to discern whether content validity has been achieved (European Medicines Agency Committee for Medicinal Products for Human Use, 2005; U.S. Department of Health and Human Services, 2009). In the absence of further information, and recent qualitative research suggesting aspects of DD that are not captured in these measures (Balfe et al.,

2013; Tanenbaum et al., 2016), it does not appear that any single existing measure of DD meets required standards for assuring content validity or offers a fully comprehensive measure of DD.

4.1 Limitations of identified measures

In terms of the six measures that we identified, some important caveats are noteworthy. These measures are variable in the extent to which they provide a direct measure of the nature or amount of emotional distress experienced in relation to a stressor and instead elicit an appraisal of a stressor (and the extent to which this bothers them). Exemplar items from the DDS are 'Feeling overwhelmed with the demands of living with diabetes' and 'Feeling that I am not testing my blood sugars frequently enough' respectively. This issue may partly explain inconsistency in studies that have attempted to empirically distinguish DD and depressive symptoms (Gonzalez, Fisher, & Polonsky, 2011).

Such nuances in item wording may also introduce content overlap with measures of other constructs. For example, the DDS item 'Feeling that I am not testing my blood sugars frequently enough' captures feelings of guilt and self-blame etc. associated with blood glucose testing but also success in executing self-management behaviors. This may explain inconsistency in associations between DD and self-management behaviors (Aikens, 2012; Gonzalez, Delahanty, Safren, Meigs, & Grant, 2008). Indeed some recent studies have restricted analyses of the association between diabetes distress and self-management to the emotional-burden sub-scale of the DDS to avoid contamination (Gonzalez, Shreck, Psaros, & Safren, 2015).

4.2 Strengths and limitations of the research

We applied a rigorous and systematic approach to identifying measures of DD, some of which have not previously been considered for this purpose, distinguishing these from other measures that may, mistakenly, be considered to measure DD. We have also brought to the fore that existing measures of DD differ in their focus and scope and have offered recommendations about the context-specific utility of each measure (European Medicines Agency Committee for Medicinal Products for Human Use, 2005; U.S. Department of Health and Human Services, 2009).

This review is not without limitations, though. This was not a systematic review, albeit the measures identified were derived from a systematic search for studies that measured DD during which over 16,000 references were screened (Dennick et al., 2016; Sturt, Dennick, Hessler, et al., 2015). Moreover, we applied an arbitrary threshold (at least 75% items focusing on DD) for a measure to be considered to assess DD. In the absence of any convention, we considered this a reasonable threshold to indicate a focus on DD. There was a tangible distinction between measures that met this criterion and those that did not. We were unable to obtain the completion instructions and/or scoring key for some measures, hence they could not be considered in their entirety (i.e. Well-being Enquiry for Diabetes (WED) (Mannucci, Ricca, Bardini, & Rotella, 1996) and Diabetes 39 (D39) (Carey et al., 1991). It is unlikely, however, that this information would alter the conclusion that these are not appropriate measures of DD. Finally, we did not assess the utility of published short forms such as the PAID-5 (McGuire et al., 2010) and DDS-2 (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008). As the field moves forward, it is likely that these measures will become more widely used as screening tools and these questions may require revision.

4.3 Future directions

In the absence of detailed information about the development work underpinning the identified measures, and qualitative work suggesting omissions, supplementary work may be required to revise a measure, or measures, of DD that achieve content validity for their specific objective, and indeed publications that report on this, are warranted. Such endeavors need to be mindful of item wording, such that a direct assessment of the emotional distress experienced is attained and

content overlap with measures of other constructs is avoided. The work that has recently been undertaken in devising a measure specific to the unique issues experienced by people with type 1 diabetes should perhaps be mirrored specifically in type 2 diabetes with attention to recent evidence reporting on qualitative distinctions in the source of DD according to treatment regimen (e.g. insulin versus oral therapies) (Tanenbaum et al., 2016). The development work underpinning the PAID and DDS did not distinguish between different types of diabetes, and recent evidence suggests type-specific measures are warranted (Fenwick et al., 2016). The main purpose of measures of DD is likely to remain to evaluate service delivery, medications, education or other interventions. Hence, further work is required to ensure that scientific measurement of DD meets international standards for use in clinical trials.

4.4 Implications of the findings

In terms of currently available measures, we anticipate that this review will enable clinicians and researchers to better identify the most appropriate measure for their purpose. When selecting a measure of DD, it is pertinent to ask the following questions:

- What is my population: Type 1 or Type 2 diabetes?
- What is my purpose in measuring DD; is my intention to capture a greater breath of the construct or is a shorter measure assessing a single, more focused construct sufficient/appropriate?
- (For observational studies and clinical audits): Which aspects of DD do I want to measure/quantify?
- (For experimental studies and interventional care pathways): What aspect of DD am I targeting/do I anticipate will be influenced by the intervention?

Once these parameters have been established, Table 3 can be used to guide selection of DD measures. For example, for an intervention targeting treatment-regimen distress in adults with type 1 diabetes, the T1-DDS would likely maximize responsiveness in outcome measurement. It should also be noted that readers may wish to consider using (any combination of) psychometrically-validated sub-scales of the DDS, T1-DDS and W-BQ28, when these more narrowly defined elements of DD better suit the intended purpose. Similarly, readers may also wish to consider the additional eight scales/sub-scales considered to capture specific elements of DD but excluded from this review due to their limited scope (see Table 1).

5 Conclusions

We have presented a conceptualization and operationalization of DD, isolated six appropriate measures of DD, distinguished them from other related measures, and offered guidance on their context-specific selection. Further research may be required to optimize the content validity of the measures identified in terms of assessing DD to meet international standards for use in clinical trials. Across the available measures, though, DD is seemingly comprehensively assessed and measures should be considered in terms of their focus and scope to ensure that the foci of interventions are appropriately targeted.

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Conflicts of interest

None.

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Appendix: Citations associated with the excluded measures

Citations associated with each of the excluded measures and results from the citation search for these measures.

Measure	Citations	Total No. citations	Most recent citation
[a]**Measures not appropriately validated**			
Diabetes-Related Knowledge and Psychosocial Functioning Questionnaire	Gilden, J. L., Hendryx, M., Casia, C., & Singh, S. P. (1989). The effectiveness of diabetes education programs for older patients and their spouses. J Am Geriatr Soc, 37(11), 1023-1030. Gilden, J. L., Hendryx, M. S., Clar, S., Casia, C., & Singh, S. P. (1992). Diabetes support groups improve health care of older diabetic patients. J Am Geriatr Soc, 40(2), 147-150.	NA	
Quality of Life with Diabetes (LDQ) scale	Fenwick, E. K., Rees, G., Holmes-Truscott, E., Browne, J. L., Pouwer, F., & Speight, J. (2016). What is the best measure for assessing diabetes distress? A comparison of the Problem Areas in Diabetes and Diabetes Distress Scale: results from Diabetes MILES-Australia. J Health Psychol, pii: 1359105316642006. Hirsch, A., Bartholomae, C., & Volmer, T. (1997). General and disease specific quality of life measures in people with diabetes. Paper presented at the 13th Annual Meeting of the International Society of Technology Assessment in Health Care, Barcelona. Hirsch, A., Bartholomae, C., & Volmer, T. (2000). Dimensions of quality of life in people with non-insulin-dependent diabetes. Qual Life Res, 9(2), 207-218.	NA	
Diabetes Symptom Distress Questionnaire	Anderson, R. , & Testa, M. (1994). Symptom distress checklists as a component of quality of life measurement. Drug Inf J, 28(89-114).	NA	
Perceived Threat of Diabetes	Connell, C. M., Davis, W. K., Gallant, M. P., & Sharpe, P. A. (1994). Impact of social support, social cognitive variables, and perceived threat on depression among adults with diabetes. Health Psychol, 13(3), 263-273.	NA	
Diabetes-Related Stress	Dalfrà, M.G., Nicolucci, A., Bisson, T., Bonsembiante, B., & Lapolla, A. (2012). Quality of life in pregnancy and post-partum: a study in diabetic patients. Qual Life Res, 21(2), 291-298. De Berardis, G., Franciosi, M., Belfiglio, M., Di Nardo, B., Greenfield, S., Kaplan, S.H., . . . The Quality of Care and Outcomes in Type 2 Diabetes (QuED) Study Group. (2002). Erectile dysfunction and quality of life in type 2 diabetic patients: a serious problem too often overlooked. Diabetes Care 25(2), 284-291.	NA	
Diabetes Health Distress	Dalfrà, M.G., Nicolucci, A., Bisson, T., Bonsembiante, B., & Lapolla, A. (2012). Quality of life in pregnancy and post-partum: a study in diabetic patients. Qual Life Res, 21(2), 291-298. De Berardis, G., Franciosi, M., Belfiglio, M., Di Nardo, B., Greenfield, S., Kaplan, S.H., . . . The Quality of Care and Outcomes in Type 2 Diabetes (QuED) Study Group. (2002). Erectile dysfunction and quality of life in type 2 diabetic patients: a serious problem too often overlooked. Diabetes Care 25(2), 284-291.	NA	
Diabetes Hassles Questionnaire	Cox, D. J., Taylor, A. G., Nowacek, G., Holleywilcox, P., Pohl, S. L., & Guthrow, E. (1984). The Relationship between Psychological Stress and Insulin-Dependent Diabetic Blood-Glucose Control - Preliminary Investigations. Health Psychol, 3(1), 63-75. Weinger, K., & Jacobson, A. M. (2001). Psychosocial and quality of life correlates of glycemic control during intensive treatment of type 1 diabetes. Patient Educ Couns, 42(2), 123-131.	NA	
Diabetes Impact Survey	(no reference identified)	NA	

Measure	Citations	Total No. citations	Most recent citation
Diabetes Emotional Impact Questionnaire	(no reference identified)	NA	
The Diabetes Questionnaire (TDQ)	(no reference identified)	NA	
[b]**Measures not indexed in database to facilitate citation search**			
The Diabetes Quality of Life Brief Clinical Inventory	Burroughs, T.E., Desikan, R., Waterman, B.M., Gilin, D., & McGill, J. (2004). A brief, treatment-focused version of the Diabetes Quality of Life (DQOL) questionnaire for use with both type 1 and type 2 diabetes. Diabetes Spectr, 17(1), 41-49.	NA	
Elderly Diabetes Burden Scale (EDBS)	Araki, A., & Ito, H. . (2003). Development of elderly diabetes burden scale for elderly patients with diabetes mellitus. Geriatr Gerontol Int, 3, 212-222.	NA	
Diabetes Quality of Life Questionnaire (DQLQ)	Henderson, M.J., & Tindall, H. (1990). Evaluation of consumer satisfaction and quality of life in patients changing to Novopen II. Practical Diabetes International, 7, 206-208.	NA	
The Problem Areas in Life with Diabetes (PLD) questionnaire	Kulzer, B, Bauer, U., Hermanns, H., & Bergis, K.H. (1995). Entwicklung eines Problemfragebogens für Diabetiker zur Identifikation von Schulungseinheiten im Umgang mit der Krankheit. Verhaltenstherapie, 5(Suppl 1), 72.	NA	
The Ideas About Diabetes—Revised (IAD-R) scale	Dion, G.A. (1990). Testing of an instrument to measure acceptance of diabetes: Ideas About Diabetes—Revised (IAD-R). Louisiana State University, New Orleans.	NA	
Diabetes-specific Stress Perceptions (DSSP) scale	Su, Y.L., Zhang, M., & Chen, Y.Z. (1994). The relationship of stress perceptions and coping of non-insulin-dependent diabetes mellitus patients in a outpatient department. Nursing Research (Taiwan, China), 2, 30-40.	NA	
[c]**Measures not assessing the personal impact of diabetes**			
Diabetes Obstacles Questionnaire (DOQ)	Hearnshaw, H., Wright, K., Dale, J., Sturt, J., Vermeire, E., & van Royen, P. (2007). Development and validation of the Diabetes Obstacles Questionnaire (DOQ) to assess obstacles in living with Type 2 diabetes. Diabet Med, 24(8), 878-882.	NA	
Diabetes Care Profile (DCP)	Fitzgerald, J. T., Davis, W. K., Connell, C. M., Hess, G. E., Funnell, M. M., & Hiss, R. G. (1996). Development and validation of the Diabetes Care Profile. Eval Health Prof, 19(2), 208-230.	NA	
The Diabetes Integration Scale (ATT39)	Dunn, S. M., Smartt, H. H., Beeney, L. J., & Turtle, J. R. (1986). Measurement of emotional adjustment in diabetic patients: validity and reliability of ATT39. Diabetes Care, 9(5), 480-489. Welch, G., Beeney, L., Dunn, S.M., & Smith, R.B.W. (1996). The development of the diabetes integration scale: a psychometric study of the ATT39. Multivariate Experimental Clinical Research, 11(2), 75-88.	NA	
Diabetes Attitudes Scale (DAS)	Anderson, R.M., Donnelly, M.B., Gressard, C., & Dedrick, R.F. (1989). The development of a diabetes attitude scale for health care professionals. Diabetes Care, 12, 120-127.	NA	
The Barriers to Insulin Treatment Questionnaire	Petrak, F., Stridde, E., Leverkus, F., Crispin, A. A., Forst, T., & Pfutzner, A. (2007). Development and validation of a new measure to evaluate psychological resistance to insulin treatment. Diabetes Care, 30(9), 2199-2204.	NA	
The Personal Diabetes Questionnaire (PDQ)	Stetson, B., Schlundt, D., Rothschild, C., Floyd, J. E., Rogers, W., & Mokshagundam, S. P. (2011). Development and validation of The Personal Diabetes Questionnaire (PDQ): a measure of diabetes self-care behaviors, perceptions and barriers. Diabetes Res Clin Pract, 91(3), 321-332.	NA	
The Barriers in Diabetes Questionniare	Mollem, E. D., Snoek, F. J., & Heine, R. J. (1996). Assessment of perceived barriers in self-care of insulin-requiring diabetic patients. Patient Educ Couns, 29(3), 277-281. Willemse, G. (1989). Waargenomen barrieres bij diabetespatienten (Perceived barriers in diabetic patients). PhD, Catholic University Brabant, Tilburg.	NA	
The Acceptance and Action Questionniare - II (AAQ-II) (diabetes version)	Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., . . . Zettle, R. D. (2011). Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. Behav Ther, 42(4), 676-688.	NA	

Measure	Citations	Total No. citations	Most recent citation
	Gregg, J. A., Callaghan, G. M., Hayes, S. C., & Glenn-Lawson, J. L. (2007). Improving diabetes self-management through acceptance, mindfulness, and values: a randomized controlled trial. J Consult Clin Psychol, 75(2), 336-343. Schmitt, A., Reimer, A., Kulzer, B., Haak, T., Gahr, A., & Hermanns, N. (2014). Assessment of diabetes acceptance can help identify patients with ineffective diabetes self-care and poor diabetes control. Diabet Med, 31(11), 1446-1451. Schmitt A, Gahr A, Hermanns N, Kulzer B, Haak T. (2013). Evaluation der deutschen Fassung des Fragebogens AADQ zur Diabetesakzeptanz: der Acceptance and Action Diabetes Questionnaire in Deutscher fassung eignet sich fur wissenschaft und klinik. *Diabetes Stoffw Herz, 22*.		
[d]**Measures that could not be obtained**			
Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ-R)	Shen, W., Kotsanos, J. G., Huster, W. J., Mathias, S. D., Andrejasich, C. M., & Patrick, D. L. (1999). Development and validation of the Diabetes Quality of Life Clinical Trial Questionnaire. Med Care, 37(4 Suppl Lilly), AS45-66.	NA	
[e]**Measures assessing the personal impact of diabetes but not meeting citation criteria**			
Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ)	Snoek, F. J., Mollema, E. D., Heine, R. J., Bouter, L. M., & van der Ploeg, H. M. (1997). Development and validation of the diabetes fear of injecting and self-testing questionnaire (D-FISQ): first findings. Diabet Med, 14(10), 871-876.	19	AUG 2013
Diabetes Diet-related QoL Scale	Sato, E., Suzukamo, Y., Miyashita, M., & Kazuma, K. (2004). Development of a diabetes diet-related quality-of-life scale. Diabetes Care, 27(6), 1271-1275.	5	JAN 2013
Diabetes Impact Measurement Scales (DIMS)	Hammond, G. S., & Aoki, T. T. (1992). Measurement of health status in diabetic patients. Diabetes impact measurement scales. Diabetes Care, 15(4), 469-477.	40	OCT 2013
Newcastle Diabetes Symptoms Questionnaire (NDSQ)	McColl, E., Steen, I. N., Meadows, K. A., Hutchinson, A., Eccles, M. P., Hewison, J., . . . Blades, S. M. (1995). Developing outcome measures for ambulatory care--an application to asthma and diabetes. Soc Sci Med, 41(10), 1339-1348.	18	SEP 2011
Diabetes Health Status Questionnaire	Wierenga, M. E. (1994). Life-style modification for weight control to improve diabetes health status. Patient Educ Couns, 23(1), 33-40.	17	DEC 2012
Diabetes Emotional Adjustment Scale (DEAS)	De Leon, O. A. (1995). Development, reliability and validation of the Diabetes Emotional Adjustment Scale in Spanish: preliminary findings. Int J Psychiatry Med, 25(1), 81-92.	1	JAN 2003
Quality of Life Scale for Diabetes Mellitus (DMQLS)	Wang, L. S., Sun, Z. Q., Cai, T. S., & Zhou, Z. G. (2005). Development and evaluation of quality of life scale for patients with type 2 diabetes mellitus. Zhong Nan Da Xue Xue Bao Yi Xue Ban, 30(1), 21-27.	3	JAN 2013
The Quality of Life Status and Change Instrument	Hornquist, J. O., Wikby, A., Hansson, B., & Andersson, P. O. (1993). Quality of life: status and change (QLsc) reliability, validity and sensitivity of a generic assessment approach tailored for diabetes. Qual Life Res, 2(4), 263-279.	17	APR 2009
Fear of Hypoglycemia Scale (FH-15)	Anarte Ortiz, M. T., Caballero, F. F., Ruiz de Adana, M. S., Rondan, R. M., Carreira, M., Dominguez-Lopez, M., . . . Soriguer, F. C. (2011). Development of a new fear of hypoglycemia scale: FH-15. Psychological assessment, 23(2), 398-405.	0	NA

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Table 1 Face validity of short-listed measures

Face validity for assessing diabetes distress of each of the nineteen short-listed measures.

Questionnaire abbreviation: name [ref(s)]	Full measure of DD; ≥75% items DD?	Sub-scale(s) measure of DD?
PAID: Problem Areas in Diabetes **(Polonsky et al., 1995)**	Yes	No sub-scales recommended
DDS: Diabetes Distress Scale **(Polonsky et al., 2005)**	Yes	Yes – 'Emotional Burden', 'Physician-related Distress', 'Regimen-related Distress' & 'Interpersonal Distress' ≥75% items DD
T1-DDS: Type 1 Diabetes Distress Scale (Fisher, Polonsky, et al., 2014; **Fisher et al., 2015**)	Yes	Yes - all sub-scales ≥75% items DD (i.e. 'Powerlessness', 'Management Distress', 'Hypoglycemia Distress', 'Negative Social Perceptions', 'Eating Distress', 'Physician Distress' & 'Friend/family Distress')
W-BQ28: Well-being Questionnaire 28-item version (Diabetes-specific Well-being sub-scale) (Bradley, 2000; Speight & Bradley, 2002; **Speight et al., 2012**).	Yes	Yes - all sub-scales ≥75% items DD (i.e. 'Diabetes-specific Negative Well-being', 'Diabetes-specific Positive Well-being' & 'Diabetes-specific Stress')
DSQoLs-R: Diabetes-specific Quality of life Scale-Revised (Burdens and Restrictions sub-scale) (Bott et al., 1998; **Cooke et al., 2013**)	No	Yes - 'Daily Hassles' ≥75% items DD No - 'Anxiety About the Future' & 'Fear of Hypoglycemia' sub-scales ≥75% items DD <u>but limited scope</u> ('Social Aspects', Dietary Restraint' & 'Physical Complaints' sub-scales <75% items DD)
IPQ-R: Illness Perceptions Questionnaire – Revised (**Moss-Morris et al., 2002**; Weinman et al., 1996)	N/A	Yes - 'Emotional Representations' ≥75% Items DD ('Identity' & 'Consequences' sub-scales <75% Items DD)
DSC-R: Diabetes Symptom Checklist-Revised (**Arbuckle et al., 2009**; Grootenhuis et al., 1994)	No	No - Neurology–sensory, Ophthalmology & Hyperglycemia sub-scales ≥75% Items DD <u>but limited scope</u> ('Psychology, cognitive', 'Psychology, fatigue', 'Neurology, pain', 'Cardiology' & 'Hypoglycemia' sub-scales <75% Items DD)
HFS-II: Hypoglycemia Fear Survey II (Cox et al., 1987)	N/A	No - 'Worry' sub-scale ≥75% Items DD <u>but limited scope</u> ('Part 2' sub-scale <75% Items DD)
DQoL: Diabetes Quality of Life measure (Jacobson, Barofsky, Cleary, Rand, & The DCCT Research Group, 1988)	N/A	No - 'Diabetes-related Worry' ≥75% Items DD <u>but limited scope</u> ('Impact' sub-scale <75% Items DD)
IITQ: Inhaled Insulin Treatment Questionnaire (Rubin & Peyrot, 2010)	N/A	No – 'Diabetes Worries' ≥75% Items DD <u>but limited scope</u>
QSD-R: Questionnaire on Stress in patients with Diabetes – Revised (Duran et al., 1995; **Herschbach et al., 1997**)	No	No – all sub-scales <75% Items DD (i.e. 'Leisure Time', 'Depression/Fear of Future', 'Hypoglycemia', 'Self-medication', 'Physical Complaints', 'Work', 'Partner' & 'Doctor-patient Relationship')
IDSRQ: Insulin Delivery Self-rating Questionnaire (Peyrot & Rubin, 2005)	N/A	No – all sub-scales <75% Items DD (i.e. 'Impact of Treatment on Daily Activities', 'Diabetes-related Worries', 'Social Burdens' & 'Psychological Well-being')
WED: Well-being Enquiry for Diabetics (Mannucci et al., 1996)	No	No – all sub-scales <75% Items DD (i.e. 'Symptoms', 'Discomfort', 'Serenity', 'impact')
DHP: Diabetes Health Profile (Meadows et al., 1996)	No	No sub-scales

ADDQoL: Audit of Diabetes-Dependent Quality of Life (Bradley et al., 1999)	No	No sub-scales
ADS: Appraisal of Diabetes Scale (Carey et al., 1991)	No	No sub-scales
MDQ: Multi-dimensional Diabetes Questionnaire (General Perceptions of Diabetes sub-scale) (Talbot et al., 1997)	N/A	No – all sub-scales <75% Items DD (i.e. 'Interference' & 'Severity')
D39: Diabetes 39 (Boyer & Earp, 1997)	No	No – all sub-scales <75% Items DD (I.e. 'Energy & Mobility', 'Diabetes Control', 'Anxiety & Worry', 'Social & Peer burden' & 'Sexual Functioning') (scoring key not available; composition of sub-scales not known but no items DD)
FOC: Fear of Complications questionnaire **(Taylor, Crawford, & Gold, 2005)**	No	No sub-scales

N/A: The full measure was not assessed rather one or more sub-scales were excluded because they did not assess the personal impact of diabetes.
Citations in bold distinguish the version of the measure and development paper that was considered.

Table 2 Measures/sub-scales capturing diabetes distress

Brief description of the measures/sub-scales capturing diabetes distress.

Questionnaire abbreviation: name [ref(s)]; Total citations (most recent year)	Relevant subscales (no. items)	Completion instructions	Example items	Response options	Development work	Psychometric properties
PAID: Problem Areas in Diabetes *320 citations (2014)*	No sub-scales recommended (20)	'Which of the following diabetes issues are currently a problem for you?'	'Feeling scared when you think about living with diabetes'[a] and 'feelings of deprivation regarding food and meals'[b]	5 point scale ('not a problem' to 'serious problem')	Items generated with 10 HCPs (including diabetes nurse specialists, dieticians and diabetologists) and during routine patient interviews (focusing on difficulties experienced in living with diabetes). Piloted on 25 insulin requiring female patients (predominantly T1D), with item revisions (Polonsky et al., 1995).	Internal reliability (α=.95) and convergent (HbA1c, general distress, psycho-social functioning, fear of hypoglycemia and disordered eating) and known groups (diabetes type) validity established in a sample of insulin requiring female patients (n=451) (Polonsky et al., 1995).
DDS: Diabetes Distress Scale *146 citations (2014)*	'Emotional Burden' (3), 'Physician-related Distress' (4), 'Regimen-related Distress' (5), 'Interpersonal Distress' (3)	'Consider the degree to which each of the items may have distressed or bothered you during the past month' (plus prompted to indicate how much they are bothered by each item not whether it is merely true and preamble - life with diabetes can be tough and result in many problems and hassles that vary in severity and the items reflect problem areas that people with diabetes may experience)	'Feeling angry, scared and/or depressed when I think about living with diabetes'[a] (Emotional Burden) and 'feeling that I am often failing with my diabetes routine'[b] (Regimen-related Distress)	6 point scale ('not a problem' to 'a very serious problem')	Items generated by people with diabetes & HCPs (including diabetes nurse specialists, dieticians, diabetologists and diabetes-knowledgeable psychologists), based on a priori domains of diabetes distress and review of PAID, QSD-R and ATT39 items (new & similar items suggested). Piloted on several small groups of patients (not described), with item revisions (Polonsky et al., 2005).	Internal reliability (α=.93) and convergent (depressive symptoms, self-care behaviour, cholesterol) and known groups (regimen type) validity were established at the full measure and sub-scale level in diverse multi-site samples of patients with Type 1 and T2D participating in larger trial and observational studies (n=683) (Polonsky et al., 2005).

T1-DDS: Type 1 Diabetes Distress Scale *No citations†*	'Powerlessness' (5), 'Management Distress' (4), 'Hypoglycemia Distress' (4), 'Negative Social Perceptions' (4), 'Eating Distress' (3), 'Physician Distress' (4), 'Friend/family Distress' (4).	'Indicate the degree to which each of the following may have been a problem for you' (plus prompted that 'a very serious problem' indicates it has been very tough over the past month and preamble – 'living with T1D can be tough and the items reflect the distressing things that people with diabetes may experience)'	'Feeling worried that I will develop serious long-term complications no matter how hard I try'[a] (Powerlessness) and 'Feeling that my eating is out of control'[b] (Eating Distress)	6 point scale ('not a problem' to 'a very serious problem')	Items generated via literature review and interviews with adult patients with T1D stratified by age, gender, and years with T1D (n=25; interviewees ere asked 'What about T1D drives you crazy?' and 'What particular aspects of diabetes are the most difficult for you?') & HCPs (n=10). Responses were reviewed for duplication, converted to survey items and reviewed by patients/HCPs for clarity. Validated in 414 patients with T1D from the USA and Canada, with item reduction (Fisher et al., 2015).	Internal reliability (α=.91 & .92 respectively) and construct validity (quality of life, depressive symptoms, fear of hypoglycemia (worry sub-scale), HbA1c, and number of complications) were established at the final full measure and sub-scale level (in the aforementioned sample) (Fisher et al., 2015)
W-BQ28: Well-being Questionnaire 28-item version ('Diabetes-specific Well-being' sub-scale) *No citations*	'Diabetes-specific Negative Well-being' (4), 'Diabetes-specific Positive Well-being' (4), 'Diabetes-specific Stress' (4)	'Circle one number to indicate how often you feel each statement has applied to you in the past few weeks' (and prompted the diabetes well-being sub-scale items are concerned with the effects of your diabetes)	'Because of my diabetes I worry about the future'[a] (Diabetes-specific Negative Well-being) and 'I feel stressed by keeping to a schedule with my diabetes' [a] (Diabetes-specific Stress)	4 point scale ('all the time' to 'not at all')	Extended version of the W-BQ12: new stress and diabetes-specific well-being/stress items were generated, but method not reported (development work published in conference abstract only [28]). Piloted on N=789 diabetes outpatients in DIABQoL+ study, with item revisions (Speight & Bradley, 2002).	Preliminary psychometric validation suggested internal reliability (at the sub-scale level α=.80-.87), test-retest reliability (.79), convergent validity (HbA1c) and sensitivity to change [28]. Internal reliability (α=.84-.90), convergent (correlations between W-BQ28 sub-scales), divergent (treatment satisfaction and self-care) and known-groups (age, gender and HbA1c) validity were subsequently confirmed at the full-scale and sub-scale level and published in a sample of people with T2D (n=353) (Speight et al., 2012).

DSQoLs-R: Diabetes-specific Quality of life Scale-Revised (Burdens and Restrictions sub-scale) *No citations*	'Daily Hassles' (5)	'Which burdens and restrictions from diabetes and its treatment have you experienced during the last 4 weeks' (plus prompted 'we want to understand to what extent diabetes bothers you in your daily life' and preamble - diabetes is for most people associated with several restrictions and burdens)	'It bothers me that I have to take my medical instruments with me whatever I do'[a] and 'It bothers me that I have to spend so much time on my diabetes treatment'[a]	6 point scale ('perfectly' to 'not at all')	Underwent a substantial revision resulting in omissions, modifications and addition of items such that the burdens and restrictions sub-scales comprise an additional 13 items, yet the validation work underpinning this has not been published. An English language version was subsequently developed (Cooke et al., 2013).	English language version demonstrated internal reliability (α=.85-.94), concurrent validity (D-SQoL), discriminant validity (depressed mood, generic QoL, and life satisfaction) and known-groups validity (presence of diabetes-related complications) at the full-scale and sub-scale level in T1D using baseline data across three UK DAFNE study sites (Cooke et al., 2013).
IPQ-R: Illness Perceptions Questionnaire – Revised *880 citations (2014)*	'Emotional Representations' (6)	'Indicate how much you agree or disagree with the following statements about your diabetes' (and prompted 'we are interested in your own personal views of how you see your diabetes')	'I get depressed when I think about my illness'[a] and 'My illness makes me feel afraid'[a]	5 point scale ('strongly disagree' to 'strongly agree')	Quantitative assessment of the 5 dimensions of cognitive representations of illness (Leventhal's Self-Regulatory Model); identity, consequences, timeline, control/cure and cause (items derived theoretically to assess these dimensions, by the authors and via patient interviews). Subsequently revised to improve measurement properties and extend scope; new items added, existing structure altered, and two subscales added; 'illness coherence' and 'emotional representations' (a previously overlooked component of Leventhal's model; items tap 6 affective responses to illness proven to be sensitive to differences in illness perceptions and predict health behaviors) (Moss-Morris et al., 2002).	IPQ-R was then validated in 8 UK patient groups including diabetes. Internal reliability (α=.79-.89) and predictive, known-groups and discriminant validity were established for full measure and sub-scales; only the latter was established in diabetes (i.e. a discriminant association with general affective disposition) (Moss-Morris et al., 2002).

N/A: Not applicable; DD: diabetes distress; T1D: Type 1 diabetes; T2D: Type 2 diabetes; BMI: body mass index; QoL: quality of life; D-SQoL: diabetes-specific QoL; HCPs: health care professionals.

[a]Emotional distress elicited via the item wording irrespective of the completion instructions or response options.

[b]Emotional distress elicited via the completion instructions or response options only.

[c]Cognitive appraisal of the personal impact of diabetes elicited: emotional distress not elicited via the item wording, completion instructions or response options.
†At the time that the citation search was undertaken only a conference paper, published within the previous three years, was available reporting on the development of the T1-DDS hence this was included as a potentially emerging measure.

Table 3 Content validity of the measures of diabetes distress

Content validity of the measures of diabetes distress highlighting variation in the operationalization of the construct.

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
Treatment regimen	Feeling guilty / a failure in relation to managing diabetes	Feelings of guilt or anxiety when you get off track with your diabetes management (#13)	Feeling that I am often failing with my diabetes routine (#6)	Feeling that I am not as skilled at managing diabetes as I should be (#1)	I worry about the management of my diabetes (#19)		
			Feeling that I am not testing my blood sugars frequently enough (#5)	Feeling that I have got to be perfect with my diabetes management (#21)			
			Not feeling confident in my day-to-day ability to manage diabetes (#10)	Feeling that I am not taking as much insulin as I should (#8)			
				Feeling that I don't check my blood glucose levels as often as I probably should (#12)			

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
				Feeling that I don't give my diabetes as much attention as I probably should (#28)			
	Feeling despondent / unmotivated regarding diabetes management	Feeling discouraged with your diabetes treatment plan (#2)	Not feeling motivated to keep up my diabetes self-management (#16)	Feeling discouraged when I see high blood glucose numbers that I can't explain (#5)	I feel a sense of satisfaction from managing my diabetes (#26)		
				Feeling that no matter how hard I try with my diabetes, it will never be good enough (#25)			
	Feeling burdened by diabetes management			Feeling that there is too much diabetes equipment and stuff I must always take with me (#9)	I feel stressed by keeping to a schedule with my diabetes (#23)	It bothers me that I have to spend so much time on my diabetes treatment (#1)	
						It bothers me that I have to measure my blood glucose so often (#1)	

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
					I feel positive about my diabetes management (#27)	It bothers me that I have to take my diabetes supplies (e.g. blood testing equipment) with me whatever I do (#45)	
Food / eating	Feeling deprived regarding food and eating	Feelings of deprivation regarding food and meals (#5)					
	Feeling pre-occupied and controlled by dietary requirements	Feeling constantly concerned about food and eating (#11)		Feeling that thoughts about food and eating control my life (#16)		It is a burden for me that I need to constantly think about my food plan (#2)	
	Feeling unable to comply with dietary requirements		Feeling that I am not sticking closely enough to a good meal plan (#12)	Feeling that I don't eat as carefully as I probably should (#2) Feeling that my eating is out of control (#23)			

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
Negative emotional experiences related to diabetes	Feeling overwhelmed by diabetes	Feeling that diabetes is taking up too much of your mental and physical energy every day (#16)	Feeling that diabetes is taking up too much of my mental and physical energy every day (#1)				
	Experiencing negative affect relating to diabetes	Feeling depressed when you think about living with diabetes (#6)	Feeling angry, scared, and/or depressed when I think about living with diabetes (#3)		Talking or thinking about my diabetes gets me upset or feeling downhearted (#17)		I get depressed when I think about my diabetes (#1)
		Feeling scared when you think about living with diabetes (#3)			Because of my diabetes I get depressed (#18)		Having diabetes makes me feel anxious (#5)
		Feeling angry when you think about living with diabetes (#10)			I feel irritated by my diabetes (#24)		When I think about my illness I get upset (#2)
					I feel frustrated that I have to live with diabetes (#22)		My diabetes makes me feel afraid (#6)
							My diabetes makes me feel angry (#3)

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
	Feeling overwhelmed / burned out because of diabetes	Feeling that diabetes is taking up too much of your mental and physical energy every day (#16)	Feeling that diabetes is taking up too much of my mental and physical energy every day (#1)		Managing my diabetes means I have too many things to do (#21)		
		Feeling overwhelmed by your diabetes (#8)	Feeling overwhelmed by the demands of living with diabetes (#14)		I feel I can cope with the challenges my diabetes might present (#28)		
		Feeling 'burned out' by the constant effort needed to manage diabetes (#20)					
	Acceptance of diabetes	Not 'accepting' your diabetes (#14)			I feel well adjusted to my diabetes (#25)		My diabetes does not worry me (#4)
	Feeling confused about the emotional impact of diabetes	Not knowing if your mood or feelings are related to your diabetes (#7)					
	Feeling controlled by diabetes		Feeling that diabetes controls my life (#8)			It bothers me how much diabetes controls my life (#53)	

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
Future / complications	Fear of complications/ the future	Worrying about the future and the possibility of complications (#12)	Feeling that I will end up with serious long-term complications, no matter what I do (#11)	Feeling worried that I will develop serious long-term complications no matter how hard I try (#13)	Because of my diabetes I worry about the future (#20)		
	Coping with existing complications	Coping with complications of diabetes (#19)					
Hypoglycemia	Worry about hypoglycemia	Worrying about low blood sugar reactions (#9)		Feeling frightened that I could have a serious hypoglycemic event when I'm asleep (#15)			
				Feeling frightened that I could have a serious hypoglycemic event while driving (#22)			
				Feeling that I can't ever be safe from the possibility of a hypoglycemic event (#27)			

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
	Worry about hypoglycemic unawareness			Feeling that I don't notice the warning signs of hypoglycemia as well as I used to (#3)			
Social / interpersonal	Unhelpful behaviour from friends and family relating to diabetes	Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat) (#4)		Feeling that my family and friends make a bigger deal out of diabetes than they should (#6)			
				Feeling that my friends of family act like "diabetes police" (bother me too much) (#20)			
	Feeling that friends and family do not understand		Feeling that friends of family don't appreciate how difficult living with diabetes can be (#13)				

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
	Feeling unsupported by friends and family in relation to diabetes	Feeling that your friends and family are not supportive of your diabetes management efforts (#18)	Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the 'wrong' foods) (#7)				
	Feeling alone with diabetes	Feeling alone with your diabetes (#17)	Feeling that friends or family don't give me the emotional support that I would like (#17)***	Feeling that I have to hide my diabetes from other people (#10)			
	Feeling that people treat you differently because of diabetes			Feeling that my friends and family worry more about hypoglycemia than I want them to (#11)			
				Feeling that my friends or family treat me as if I were more fragile or sicker than I really am (#17)***			

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
				Feeling that people treat me differently when they find out I have diabetes (#4)			
				Feeling that people will think less of me when if they knew I had diabetes (#24)			
	Fear of discrimination in relation to employment			Feeling concerned that diabetes may make me less attractive to employers (#19)			
Health care professionals	Feeling that HCPs do not have enough knowledge about diabetes		Feeling that my doctor doesn't know enough about diabetes and diabetes care (#2)	Feeling that my doctor doesn't know enough about diabetes and diabetes care (#26)			
				Feeling that my diabetes doctor doesn't really understand what it's like to have diabetes (#18)			

Aspect of DD		**PAID:** Problem Areas in Diabetes (20 items)	**DDS:** Diabetes Distress Scale (17 items)	**T1-DDS:** Type 1 Diabetes Distress Scale (28 items)	**W-BQ28:** Well-being Questionnaire 28 ('Diabetes Well-being' sub-scale) (12 items)	**DSQoLs-R:** Diabetes-specific Quality of life Scale-Revised ('Daily Hassles' sub-scale) (5 items)	**IPQ-R:** Illness Perceptions Questionnaire – Revised ('Emotional Representations' sub-scale) (6 items)
	Negative emotion about diabetes self-management goals from HCPs	Not having clear and concrete goals for your diabetes care (#1)	Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes (#4)				
	Feeling unsupported by HCPs		Feeling unsatisfied with your diabetes physician (#15)	Feeling that I don't get help I really need from my diabetes doctor about managing diabetes (#14)			
			Feeling that I don't have a doctor who I can see regularly enough about my diabetes (#15)	Feeing that I can't tell my diabetes doctor what is really on my mind (#7)			
			Feeling that my doctor doesn't take my concerns seriously enough (#9)***				

DD: diabetes distress; HCPs: Health care professionals.

Figure 1 Flow diagram

NA: Not applicable
PAID: Problem Areas in Diabetes; DDS: Diabetes Distress Scale; DDS (T1): Type 1 Diabetes Distress Scale; DSQoLS-R: Diabetes-specific Quality of life Scale-Revised; W-BQ 28: Well-being Questionnaire 28; IPQ-R: Illness Perceptions Questionnaire – Revised; DSC-R: Diabetes Symptom Checklist-Revised; HFS-II: Hypoglycemia Fear Survey II; DQoL: Diabetes Quality of Life measure; IITQ: Inhaled Insulin Treatment Questionnaire; QSD-R: Questionnaire on Stress in patients with Diabetes – Revised; IDSRQ: Insulin Delivery Self-rating Questionnaire; WED: Well-being Enquiry for Diabetics; DHP: Diabetes Health Profile; ADDQoL: Audit of Diabetes-Dependent QOL instrument; MDQ: Multi-dimensional Diabetes Questionnaire; D39: Diabetes 39; FOC: Fear of Complications questionnaire.

Highlights

- This paper presents a conceptualization and operationalization of diabetes distress based on the extant evidence base; DD is characterized by a range of negative emotional responses (e.g. worry, fear, frustration, guilt, sadness, anger, overwhelm), to aspects of living with and managing diabetes balanced against an appraisal of available coping resources.

- This paper distinguishes six measures of diabetes distress from the vast array of diabetes-specific patient-reported outcome measures in existence, only three of which have previously been considered for this purpose.

- This paper brings to the fore that existing measures of DD differ in their focus and scope; none appears to be fully comprehensive and hence selection decisions should be informed by consideration of their unique focus and scope to ensure that the foci of interventions are appropriately targeted.